Booklet for healthy lifestyle in people with HIV: a clinical trial

Cartilha para estilo de vida saudável em pessoas com HIV: ensaio clínico

Cartilla de estilo de vida saludable para personas con VIH: ensayo clínico

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Abstract

Objective: To assess the effectiveness of an educational booklet to promote healthy lifestyle and antiretroviral compliance in people with HIV.

Methods: This is a randomized clinical trial at an outpatient clinic in Fortaleza, Ceará, Brazil, with 70 patients in the intervention group and 74 in the control group. People with HIV over 18 years of age, of both sexes, on antiretroviral therapy for more than six months, with a landline or cell phone, and 35 or more points on the Health Literacy Scale were included. Data collection took place in four moments, using the Individual Lifestyle Profile Scale and the Assessment of Antiretroviral Therapy Compliance Questionnaire (*Cuestionario para la Evaluación de la Adhesión al Tratamiento Antirretroviral*). The control group received routine medical consultation, and the intervention group, in addition to routine consultation, read the booklet in the office, and then took it home. Non-parametric analysis of variance of repeated measures was used for statistics.

Results: Most participants had an unsatisfactory lifestyle at baseline. The booklet improved patients' lifestyle after two ($P<0.001$), four ($P<0.001$) and six months ($P<0.001$) of intervention, when comparing the different times to baseline and control. There was an improvement in antiretroviral compliance scores in the intervention group when compared to baseline ($P<0.001$) and control ($P<0.001$).

Conclusion: The booklet was effective in promoting a healthy lifestyle and improving antiretroviral compliance in people with HIV, therefore, it can complement outpatient consultations.

Resumo

Objetivo: Avaliar a efetividade de uma cartilha educativa para promoção do estilo de vida saudável e adesão aos antirretrovirais em pessoas com HIV.

Métodos: Ensaio clínico randomizado em ambulatório de Fortaleza, Ceará, Brasil, com 70 pacientes no grupo intervenção e 74 no controle. Critérios de inclusão: pessoas com HIV maiores de 18 anos, de ambos os sexos, em terapia antirretroviral por mais de seis meses, ter telefone fixo ou celular, e 35 ou mais pontos na Escala de Letramento em Saúde. A coleta de dados ocorreu em quatro momentos, utilizando-se a Escala de Perfil do Estilo de Vida Individual e o Questionário para Avaliação da Adesão ao Tratamento Antirretroviral. O grupo controle recebeu a consulta médica de rotina, e o grupo intervenção, além da consulta de rotina, realizou a leitura da cartilha em consultório, e depois levou-a para o domicílio. Na estatística, utilizou-se análise de variância não paramétrica de medidas repetidas.

Resultados: A maioria dos participantes tinha estilo de vida insatisfatório na avaliação basal. A cartilha melhorou o estilo de vida dos pacientes após dois ($P<0,001$), quatro ($P<0,001$) e seis meses ($P<0,001$) da intervenção, quando comparados os diferentes tempos ao valor basal e ao controle. Houve melhora dos escores de adesão aos antirretrovirais no grupo intervenção quando comparado à linha de base ($P<0,001$) e ao controle ($P<0,001$).

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Conflicts of interest: nothing to declare.

Conclusão: A cartilha foi efetiva para promover estilo de vida saudável e melhorar a adesão aos antirretrovirais em pessoas com HIV, portanto, pode complementar as consultas ambulatoriais.

Resumen

Objetivo: Evaluar la efectividad de una cartilla educativa para la promoción del estilo de vida saludable y adhesión a los antirretrovirales para personas con VIH.

Métodos: Ensayo clínico aleatorizado en consultorios externos de Fortaleza, estado de Ceará, Brasil, con 70 pacientes en el grupo experimental y 74 en el de control. Criterios de inclusión: personas con VIH mayores de 18 años, de ambos sexos, en tratamiento antirretroviral por más de seis meses, con teléfono fijo o celular y con 35 puntos o más en la Escala de Alfabetización en Salud. La recolección de datos se realizó en cuatro momentos, mediante la Escala de Perfil del Estilo de Vida y el Cuestionario para la Evaluación de la Adhesión al Tratamiento Antirretroviral. El grupo de control recibió una consulta médica de rutina, y el grupo experimental, además de la consulta de rutina, leyó la cartilla en el consultorio y después se la llevó a su casa. En la estadística, se usó el análisis de varianza no paramétrico de medidas repetidas.

Resultados: La mayoría de los participantes tenía un estilo de vida insatisfactorio en la evaluación de base. La cartilla mejoró el estilo de vida de los pacientes después de dos (P<0,001), cuatro (P<0,001) y seis meses (P<0,001) de la intervención, si se lo compara con los diferentes tiempos al valor de base y al control. Se observó una mejora de la puntuación de adhesión a los antirretrovirales en el grupo experimental si se lo compara con la línea de base (P<0,001) y con el control (P<0,001).

Conclusión: La cartilla fue efectiva para promover un estilo de vida saludable y mejorar la adhesión a los antirretrovirales en personas con VIH; por lo tanto, puede complementar las consultas de los consultorios externos.

Brazilian Clinical Trial Registry (ReBEC): RBR-7p6vsr

Introduction

Human Immunodeficiency Virus (HIV) treatment with antiretrovirals contributed to the transition of the disease from an acute to a chronic condition.[1] However, an increased frequency of noncommunicable diseases (NCDs) is evident in these patients, and the care previously focused on opportunistic infections was expanded to other health changes that also affect the general population so that health promotion became relevant to maintaining quality of life.[2]

It is not well established whether the development of NCDs in people living with HIV (PLHIV) occurs due to increased survival with antiretroviral therapy (ART) and its long-term adverse events, whether it is related to HIV itself, or whether these factors contribute in a jointly for the occurrence of diseases.[3] However, it is known that an unhealthy lifestyle is a major factor in the emergence and maintenance of NCDs, as it is a common finding in PLHIV, especially sedentary behavior, which may be related to HIV-related stigma,[4] in addition to inadequate nutrition,[5] smoking and use of alcohol and other drugs, which were associated with worse results in HIV treatment. [6]

In this context, previous studies have pointed out the need for health interventions to improve HIVHIV's lifestyle.[7,8] For these interventions, some technology that goes beyond the office would be important, in order to represent a continued and additional care for these patients, which is why we chose to use an educational booklet for this purpose. This is an easy-to-understand technology for patients with higher education and income, as well as for those with scarce financial resources and restricted access to the internet; however, before use, they must be assessed for their effectiveness.[9,10]

Technologies for providing care are interaction tools, and booklets favor health education by simply addressing information. Quality educational materials can enable interventions based on structured knowledge, and for PLHIV, such interventions can develop positive behaviors and improve the bond with health professionals.[9]

This research is relevant due to the need to care for HIV-based HIV patients. The study contributes to scientific production and assistance, enabling health and care promotion, which can reduce long-term financial costs caused by an unhealthy lifestyle. The hypothesis was that the booklet promotes a healthier lifestyle in PLHIV, considering aspects such as nutrition, physical exercise, preventive behavior, relationships, stress management and antiretroviral drug compliance, which is the only available treatment. This study aimed to assess the effectiveness of an educational booklet to promote a healthy lifestyle and ART compliance in PLHIV.

Methods

This is a randomized controlled clinical trial, developed at the infectology outpatient clinic of a referral hospital in Fortaleza, Ceará, Brazil. Data were collected from January 2019 to July 2020. The study population consisted of PLHIV who were followed on an outpatient basis.

The sample was sized to provide a power of 90% and 95% confidence to detect a significant difference between the intervention and control groups regarding the proportion of patients who improved at least 20% in the Individual Lifestyle Profile (PEVI - *Perfil do Estilo de Vida Individual*) score.[11] It was established that a difference of 25% should be detected between the groups for the booklet effectiveness, i.e., the booklet would increase by at least 25% the proportion of patients with a minimum improvement of 20% in the PEVI score. A percentage of 15% was added for follow-up losses, estimating a sample of 75 patients per group.

Inclusion criteria were: PLHIV over 18 years old, of both sexes, on ART for at least six months, have a landline or cell phone, be able to read the booklet and have a score equal to or greater than 35 on the Health Literacy Scale.[12] Exclusion criteria were: pregnancy, disabling mental illness and being inmate. The discontinuity criteria were: desire to withdraw from the study, hospitalization, impossibility of telephone contact and death.

PLHIV were recruited through a direct approach, while waiting for a routine medical consultation, which takes place every six months. Participants who consented to participate signed the Informed Consent Form (ICF). The Health Literacy Scale,[12] translated and adapted into Brazilian Portuguese, with 14 questions and answers on a five-point Likert scale (1 to 5), which assesses literacy in 3 dimensions, functional (5 items), communicative (5 items) and critical (4 items) literacy, was applied. If the sum of points was equal to or greater than 35, literacy was adequate,[12] and the participant was randomized allocated to the intervention or control group, according to random days of the week.[13] To avoid contamination between groups, the intervention group was randomized on Mondays and Wednesdays, and on Tuesdays and Thursdays, the control. The intervention group was instructed not to share the booklet during the study. When there was more than one PLHIV in the household, they were allocated to the same group.

In the intervention stage, there was a baseline assessment of the groups with application of the instruments: sociodemographic, epidemiological, clinical and risk factor form for NCDs in PLHIV, PEVI and Assessment of Antiretroviral Therapy Compliance Questionnaire (*Cuestionario para la Evaluación de la Adhesión al Tratamiento Antirretroviral*).

The sociodemographic, epidemiological, clinical and risk factors form for NCDs in PLHIV,[14] with sex, color, education, marital status, exposure category, sexual orientation, if they have a partner and serology, religion, occupational status, family monthly income, time of diagnosis and ART, antiretrovirals, CD4+ T lymphocyte count, viral load, consumption of salt, licit and illicit drugs, physical exercise, history of NCDs, consumption of fruits, vegetables, fried foods, NCDs and drugs, blood pressure (BP), weight, height, Mass Index Body (BMI) and waist circumference.

The PEVI, validated in Brazil,[11,15] has five components: 1. nutrition; 2. physical exercise; 3. preventive behavior; 4. relationships; 5. stress management. Each component has three questions. For each question, there are four Likert-type scale response options: (0) absolutely not part of their lifestyle; (1) sometimes matches their behavior; (2) almost always truthful in their behavior; (3) the statement is always true in their daily life. The values "0" and "1" represent a negative lifestyle profile, and "2" and "3" represent a positive profile. Lifestyle was rated satisfactory (30-45 points) or unsatisfactory (< 30 points).[16]

The CEAT-VIH was used in the version translated and adapted to Brazilian Portuguese.[17] There are 20 questions and the score is obtained by the sum of all items (minimum value: 17; maximum: 89). The higher the score, the greater the ART compliance.[17] Scores were classified as adequate or good (raw score ≥ 75) and inadequate or low (raw score ≤ 74) compliance.[1 8]

After applying the instruments, a routine medical consultation was performed in the control group. In addition to routine consultation, the intervention group was given a booklet for individual reading in a private office. The researcher stood next to the patient, who did the reading alone, and after consultation, the patient took the booklet home, being instructed to read it fortnightly. The procedure lasted an average of one hour in the intervention group and 30 minutes in the control group.

The "My Motivation for Change Booklet! Practices for Promoting a Healthy Lifestyle" ("*Minha Cartilha de Motivação para Mudança! Práticas para Promoção do Estilo de Vida Saudáve*l") was built and validated in a previous study,[10] with reference in the Transtheoretical Model of Behavior Change.[19] It has 30 pages, texts, colored illustrations and six domains: body weight control; healthy eating; physical exercise; smoking, alcohol and other drugs; stress control; and drug treatment.

In the post-intervention stage, the groups were reassessed by telephone calls, in the 2nd, 4th and 6th months with the PEVI, and in the 6th month with the CEAT-VIH. Two telephone devices were used for the research. The team of nine researchers was trained with standard operating procedures. For blinding, they did not know which group they were making calls to.

There was statistician blinding in the analysis. The databases were sent in a numbered form, without the identification of the groups. Descriptive analysis included frequencies for nominal variables, mean, median, standard deviation (SD) and interquartile range for quantitative variables. Compliance and normal distribution were verified by the Shapiro-Wilk test. Differences in proportions between the nominal variables at baseline were verified by Pearson's chi-square test. When more than 25% of frequencies in contingency tables were less than five, Fisher test or its extension for RxS tables (Fisher-Freeman-Halton test) was applied. For quantitative variables, differences at baseline were analyzed by the Mann-Whitney test, by identifying variable non-normality.

To compare responses between groups, parametric analysis of variance for repeated measures was developed. But tests of sphericity and normality showed violation of assumptions, performing the non-parametric analysis of variance of repeated measures, based on the approach of the transformation of aligned stations,[20] to establish sources of variation (group, time and interaction) and explain differences in the values of response variables. This analysis was based on the F tests obtained for each source of variation. T-tests were applied to analyze the differences between aligned ranks of the intervention and control groups for each assessment moment. A significance level of 5% was adopted, considering $P<0.05$ as statistically significant. For analyses, the statistical software R version 3.2.2 was used.

The project was approved by the proposing and co-participating institutions' Research Ethics Committees, with Opinions 2,481,617 (CAAE - *Certificado de Apresentação para Apreciação Ética*/ Certificate of Presentation for Ethical Consideration, 82139318.5.0000.5054) and 2,513,172 (CAAE 82139318.5.3001.5045), according to Resolution 466/2012 of the Brazilian National Health Council. Participants signed the ICF. The study was registered in the Brazilian Clinical Trial Registry (ReBEC), with Protocol RBR-7p6vsr. The Consolidated Standards of Reporting Trials (CONSORT) references were adopted.

Results

198 PLHIV were recruited, but 30 did not meet the inclusion criteria. The study was completed by 70 participants in the intervention group and 74 in the control group (Figure 1).

Of the 144 PLHIV, most were male (61.8%), mixed race (61.1%), single (50.8%), Catholic (58.3%) and employed (59.1%). The values (mean ± SD) for the intervention and control groups were, respectively: age (44.2 ± 12.4; 40.6 ± 11.5), years of study (10.8 ± 3.5; 11, 0 ± 3.8), number of children (1.2 ± 1.8; 1.2 ± 1.9) and family income (in reais) (2,239.0 ± 1,400.0; 2,738.2 ± 2,142.6). Most were in the category of sexual exposure (93.8%), heterosexual (58.4%), with a partner (52.1%), with sero-

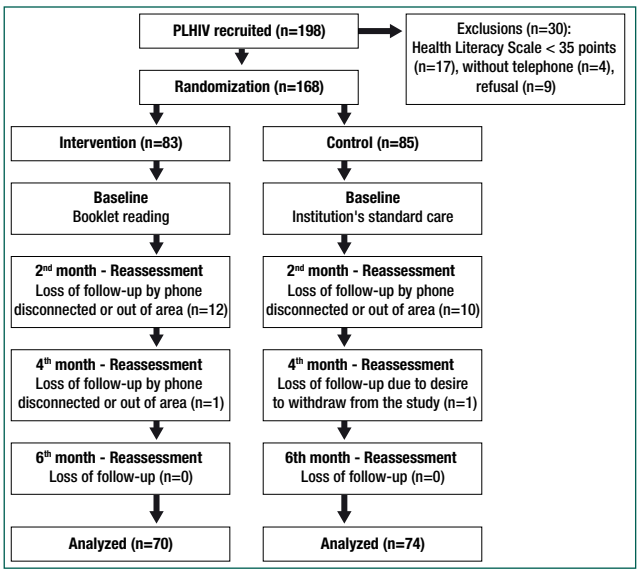

Figure 1. Study flow chart

discordant (27.1%) and seroconcordant (20.8%). The most commonly used antiretrovirals were lamivudine (93.6%) and tenofovir (79.2%). The values (mean ± SD) for the intervention and control groups were, respectively: time of diagnosis (years) (8.6 ± 5.7; 8.6 ± 5.3), time of ART (in months) (95.9 ± 59.5; 101.1 ± 65.7), CD4+ T lymphocyte count (cells/mm^3) (615.3 ± 237.6; 703.0 ± 349.1) and viral load (copies/ml) (395.6 ± 2650.0; 56.0 ± 316.9). There were people with hypertension (22.9%) and diabetes (13.9%). The majority reported moderate salt consumption (52.8%), not practicing physical exercise (53.5%), denied alcohol use (60.4%), smoking (61.8%) and illicit drugs (95.1%). Many reported family history of hypertension (76.4%), diabetes (49.3%) and cancer (49.3%). Values (mean ± SD) for the intervention and control groups were, respectively: Systolic BP (mmHg) (118.7 ± 11.9; 117.2 ± 12.8), diastolic BP (mmHg) (75.9 ± 11.9; 75.9 ± 13.3), waist circumference (cm) (88.8 ± 10.5; 89.3 ± 11.3), weight (kilograms) (70.8 ± 13.4; 71.5 ± 11.8), height (meter) (1.64 ± 0.0; 1.64 ± 0.0) and BMI (kilo/meter^2) (26.1 ± 4.5; 26.1 ± 3.4). At baseline, the intervention and control groups were comparable regarding the variables, with no statistical difference between the groups. In the PEVI analysis, the majority had an unsatisfactory lifestyle in the intervention (n=47; 67.1%; mean ± SD: 25.2 ± 8.4) and control (n=47; 63.5%; mean ± SD: 26.6 ± 8.5). The groups had a gradual increase in the PEVI score throughout the four assessments. However, the intervention group had higher mean scores in the reassessments, when compared to the control group, respectively (mean ± SD): 2nd month (31.3 ± 6.5; 27.2 ± 7.8), 4th month (34.1 ± 6.7; 29.5 ± 6.4) and 6th month (36.1 ± 6.7; 30.0 ± 6.9). The booklet implied a significant change between the groups in the different moments of assessment. Differences in the PEVI score measurement values are explained by variations such as differences between the intervention and control groups (P<0.001), intra-time differences (P<0.001) and differences in the interaction between the groups in the intra moment of assessment comparison (P<0.001). Data are detailed in Chart 1.

Chart 1. Non-parametric analysis of variance of repeated measures with verification of alignment assumption of Individual Lifestyle Profile of people living with HIV ranks for time (four moments of assessment) and group (intervention and control)

Aligned	by	Error	df*	df* residue	F**	p-value***
Time	Group	Intra	3	426	0.00	1.000
Group: time	Group	Intra	3	426	0.00	1.000
Group	Time	Subjects	1	142	0.00	1.000
Group: time	Time	Intra	3	426	0.00	1.000
Group	Group: time	Subjects	1	142	0.00	1.000
Time	Group: time	Intra	3	426	0.00	1.000
Source of variation						
Group (Subjects)			1	142	14.18	< 0.001
Time (Intra)			3	426	37.12	< 0.001
Group: time (Intra)			3	426	10.79	< 0.001

*df - degree of freedom; **F - F statistics; *** p-value - analysis of alignment assumption of transformed ranks, necessary for applying the non-parametric analysis of variance for repeated measures

The analyzes showed a statistically significant difference when comparing the baseline measurements, regardless of the group, with the measurements of the three subsequent moments (P<0.001; P<0.001; P<0.001). This fact is repeated when comparing 2nd month measurement with the subsequent ones (P=0.002; P<0.001). In other words, regarding the isolated effect of the time factor, the booklet increased the PEVI score in the intervention and control groups in the 2nd, 4th and 6th month reassessments when compared to the baseline, and increased the score in the 4th and 6th month reassessments, when compared to the 2nd month, in both groups. Analyzes showed a statistically significant difference when comparing the intervention

and control group measurements (P<0.001), regardless of time of measurement, in addition to a higher estimated marginal mean in the intervention group. Thus, as for the isolated effect of the group factor, the intervention generated a higher score on the PEVI in the intervention group compared to the control, regardless of time of measurement, as shown by Chart 2. Furthermore, the PEVI scores in the intervention and control groups were statistically different when comparing baseline to subsequent time points (P<0.001; P<0.001; P<0.001). Since the comparison method is based on difference of differences, it was concluded that the estimate's positive value referred to the highest values obtained in the intervention group. That is, as for the effect of time and group interaction, the booklet implied significantly greater changes in the intervention group compared to the control group, when comparing the baseline assessment with the 2nd, 4th and 6th month reassessments (Chart 2).

Chart 2. Post-hoc comparisons of estimated marginal means of Individual Lifestyle Profile of people living with HIV score ranks for time (four assessment moments) and groups (intervention and control), in addition to comparing the difference between pairs of groups by the differences in assessment moments

1. Time	EMM*	SE**	df ***	95% † CI	
Baseline	210	13.2	387	184 - 236	
2nd month	270	13.2	387	244 - 296	
3rd month	322	13.2	387	296 - 348	
6th month	353	13.2	387	327 - 379	
1.1 Contrasts	**Estimate**	**SE**	**df**	**t‡**	**p-value §**
Baseline - 2nd month	-59.8	14.5	426	-4.12	< 0.001
Baseline - 4th month	-111.7	14.5	426	-7.70	< 0.001
Baseline - 6th month	-142.7	14.5	426	-9.84	< 0.001
2nd month - 4th month	-51.9	14.5	426	-3.58	0.002
2nd month - 6th month	-83.0	14.5	426	-5.72	< 0.001
4th month - 6th month	-31.0	14.5	426	-2.14	0.143
2. Group	**EMM**	**SE**	**df**	**95% CI**	
Control	251	14.2	142	223 - 279	
Intervention	326	14.2	142	298 - 354	
2.1 Contrasts	**Estimate**	**SE**	**df**	**t**	**p-value**
Control - Intervention	-75.7	20.1	142	-3.77	< 0.001
3. Pairs of groups and times	**Estimate**	**SE**	**df**	**t**	**p-value**
Control – Intervention (Baseline - 2nd month)	107.7	29.8	426	3.62	< 0.001
Control – Intervention (Baseline - 4th month)	129.8	29.8	426	4.36	< 0.001
Control – Intervention (Baseline - 6th month)	158.4	29.8	426	5.32	< 0.001
Control – Intervention (2nd month - 4th month)	22.1	29.8	426	0.74	0.459
Control – Intervention (2nd month - 6th month)	50.7	29.8	426	1.70	0.089
Control – Intervention (4th month - 6th month)	28.6	29.8	426	0.96	0.337

*EMM - estimated marginal means; **SE - standard error; ***df - degree of freedom; †confidence interval; ‡t - t-tests; § P - contrast assessment

Regarding ART compliance, in the baseline assessment, the means and SD of CEAT- HIV scores in the intervention and control groups were, respectively, 74.8 ± 8.0 and 75.8 ± 6.7, and in the 6th month assessment, were 79.4 ± 5.1 and 76.8 ± 5.5. These findings revealed that the intervention group showed greater growth in mean scores when compared to the control group. Chart 3 shows the similarity between the intervention and control groups at baseline, thus being comparable. However, CEAT-HIV score values in the intervention group were higher than in the control group at the end of the experiment, as the control group did not have a significant change in the comparison of values obtained at the beginning and end of the study. On the other hand, the intervention group showed a significant increase in CEAT-HIV scores at the end of the experiment, when compared to baseline assessment. Thus, the booklet contributed to improving ART compliance.

Chart 3. Intergroup and intragroup comparisons of the Assessment of Antiretroviral Therapy Compliance Questionnaire average ranks, considering the values obtained at baseline and after six months of intervention with the educational booklet

Intergroup comparison	Rank average		W*	p-value
	Control	Intervention		
Baseline	74.75	70.12	2756.5	0.506
6 months	59.67	86.06	1640.5	<0.001
Intra-group comparison	**Baseline**	**6 months**	**V**	**p-value**
Control	70.87	78.13	390	0.151
Intervention	54.96	86.04	226	<0.001

*Wilcoxon signed rank test

Discussion

Considering lifestyle, the outcome assessed in this study, it was considered unsatisfactory for most participants in the baseline assessment, before the intervention with the educational booklet. In this context, research shows that PLHIV tend to have unhealthy behaviors, and need continuous motivation to make and maintain positive lifestyle changes, mainly due to stigma, low income and lack of social support, and regular physical exercise, adequate nutrition and cessation of smoking and alcoholism should be encouraged.[1,4-8]

The educational booklet improved PLHIV's lifestyle, which was measured using the PEVI, which

assesses nutrition, physical exercise, preventive behavior, relationships and stress management, so that the overall score was higher in the intervention group compared to the control, over time and when comparing the baseline assessment with the 2nd, 4th and 6th month reassessments. The booklet was a material of low cost and easy transportation, which patients had access to and took home to complement the outpatient consultations, with guidance on healthy lifestyle. These behavior changes can slow the virus progression, optimize the immune system and prevent opportunistic infections, metabolic, cardiovascular and lung diseases.[21]

Corroborating the findings, a study carried out in China verified the effectiveness of an intervention with a booklet on the lifestyle of pregnant women, when it was assessed in isolation and associated with counseling.[22] Another clinical trial carried out by nurses in Australia aimed at physical exercise and weight reduction in mentally ill patients through booklet intervention, which was effective in improving lifestyle.[23] Research has already concluded that three counseling sessions combined with the booklet were more effective in improving the lifestyle of women in Iran than the booklet alone.[24] Thus, the literature shows that the booklet, even in isolation, already has a positive impact and can be incorporated into health services, due to its low cost, easy understanding and handling by patients.[25]

Interventions with an impact on improving PLHIV's lifestyle are fundamental for health promotion and disease prevention, as HIV and ART in the long term are associated with an increase in cardiovascular diseases and other non-AIDS comorbidities.[26] Regarding the two initial domains of the booklet, which are body weight management and healthy eating, most participants were overweight, requiring diet and physical exercise.[21,27] The booklet provided guidance on how to maintain optimal weight and tips on healthy eating, salt reduction and industrialized products.[10,22,27]

Regarding the third domain, which is physical exercise, the material points out types of exercises and time required.[10] This aspect can improve PLHIV's immunological and physiological parameters, with increased disposition and self-esteem, prevention of lipodystrophy, dyslipidemia, insulin resistance and cardiovascular disease.[21] Clinically stable patients should practice exercises appropriate to their physical fitness, as well as assess comorbidities and situations in which exercise should be postponed, such as advanced immunodeficiency, presence of opportunistic infection or chronic conditions.[28]

In periods of social isolation due to the coronavirus-19 (COVID-19) pandemic, virtual group classes are suggested by video call for exercises and social interaction.[29] Regular physical exercise can improve immune defense, especially in risk groups. PLHIV should remain physically active, but with care that exercises are not performed with overload.[30] Staying and working at home can also affect diet and reduce the possibilities of physical exercise.[31]

Regarding the fourth domain, about smoking, alcohol and other drugs, many participants used alcohol and were smokers. The use of licit and illicit drugs by PLHIV can interfere with the action of antiretrovirals. Binding proteins have their functioning altered, as there is competition with drugs in the binding of isoenzymes of the metabolization process, in addition to a greater risk of toxicity and inefficiency, due to inadequate drug concentration in the plasma, as well as the development of pancreatitis.[26] A systematic review has also shown that more than one third of PLHIV are smokers and, therefore, exposed to substances that contribute to the occurrence of cardiovascular, respiratory and cancer diseases.[32] Moreover, drug use increases risk behaviors and HIV transmission, so the booklet recommends not using them, as well as encouraging the search for specialized care, if necessary.[10]

The fifth domain was about stress management. In this regard, a study showed that living with HIV is permeated by feelings of fear, death and sadness, [33] which represents a source of stress, which has been associated with worse psychological adjustment, depression, anxiety, risk behaviors, decreased quality of life and disease progression.[34] Interventions, such as the booklet assessed in this study, capable of guiding conducts to reduce stress, may be an option to work on this issue in patients.[33,34] Among the behaviors are managing time, avoiding extreme de-

mands, breathing deeply, valuing each achievement and forgiving.[10]

The last area addressed in the booklet was drug treatment. For PLHIV, ART compliance is a prerequisite for a healthy lifestyle, adequate CD4+ T lymphocyte count, and reduced viral load. The booklet improved ART compliance, which is an important aspect of working with these patients, as inadequate compliance leads to the emergence of resistant viral strains, disease progression and increased HIV transmission.[10,35] The booklet highlights the importance of proper compliance and strategies for remembering to take medications.[10]

One of the limitations was the fact that the booklet was assessed only with outpatients, because in the context of hospitalization or deprivation of liberty, many suggested activities could not be performed. Telephone and non-face-to-face reassessments were also a limitation, due to the fact that patients routinely return to the clinic only every six months, as well as the COVID-19 pandemic postponed consultations and interfered with PLHIV to practice all the guidelines in the booklet, especially regarding physical exercise, as social isolation restricted some activities.

Based on the results, using this booklet by multidisciplinary health teams is recommended, in addition to outpatient consultations, especially for PLHIV with limited technological access. We emphasize the importance of printed educational materials, which patients can read, take notes and take home, as an extension of professionals outside the office. Other clinical trials are suggested to assess strategies that improve these patients' lifestyle, as ART has made the infection a chronic condition, and these individuals need guidance to maintain their quality of life in the long term. New studies may also assess the booklet use associated with other interventions.

Conclusion

Most PLHIV had an unsatisfactory lifestyle at baseline. The booklet was effective in improving lifestyle and ART compliance, and can be used for these patients, in addition to outpatient visits.

Collaborations

Lima MAC, Cunha GH, Lopes MVO, Fontenele MSM, Siqueira LR, Ramalho AKL, Gomes MEC and Moreira LA contributed to the study design, data analysis and interpretation, article writing and approval of the final version to be published.

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